

Application No.: 09/781,388
Filed: February 13, 2001

Amendment
Page 3

C3 thickness being no thicker than the proximal cone wall thickness,
at least a portion of the balloon having a ground or chemically etched surface.

~~44. (Amended) The medical balloon of claim 42 wherein at least one balloon portion selected from the group consisting of the body portion, the proximal cone portion, the distal cone portion, the proximal waist portion, the distal waist portion and any combination thereof, has a ground surface.~~

C4 45. (Amended) The medical balloon of claim 42 wherein at least one balloon portion selected from the group consisting of the body portion, the proximal cone portion, the distal cone portion, the proximal waist portion, the distal waist portion and any combination thereof, has a chemically etched surface.

REMARKS

This Amendment is submitted in response to the Office Action dated December 26, 2001. In the Office Action, claims 27-30 and 33-46 are rejected. Claims 27-30 and 33-36 are pending. Claim 27 has been amended to recite that at least one segment has a chemically etched or ground surface. Claims 33 and 42 have been amended to recite that at least a portion of the balloon has a ground or chemically etched surface. Claims 40 and 44 have been amended to recite that the at least one balloon portion has a ground surface. Claims 41 and 45 have been amended to recite that the at least one balloon portion has a chemically etched surface.

Re 35 USC 102

Claims 30, 33-39, 42 and 46 are rejected under 35 USC 102(b) as being anticipated by Forman (US 5,733,301).

Claim 30 is directed to a medical balloon which when inflated to a desired pressure has a constant wall thickness over substantially the entire length of the balloon. Forman does not disclose a balloon which when inflated to a desired pressure has a constant wall thickness over substantially the entire length of the balloon. To the extent that the Forman balloon, as disclosed at

Application No.: 09/781,388
Filed: February 13, 2001

Amendment
Page 4

col. 8, lines 49-61 of Forman has a constant wall thickness, the balloon is not inflated. It would be expected that upon inflation of the balloon, the wall thickness would no longer be constant. Rather, the wider diameter section of the Forman balloon would be expected to have a smaller wall thickness than the narrower diameter sections of the balloon.

Claims 33-39 are directed to a medical balloon wherein at least one of the proximal waist wall thickness and the distal waist wall thickness is no thicker than at least one of the proximal cone wall thickness, the distal cone wall thickness, and the body wall thickness. At least a portion of the balloon has a ground or chemically etched surface. Forman does not disclose a balloon at least a portion of which has a ground or chemically etched surface. As such, claims 33-39 are patentable over Forman.

Claim 42 it is directed to a medical balloon comprising a distal waist wall having a thickness no thicker than the wall thickness of the proximal cone. At least a portion of the balloon has a ground or chemically etched surface. Forman does not disclose a balloon at least a portion of which has a ground surface. As such, claim 42 is patentable over Forman. Claim 46, dependent from claim 42, is similarly patentable over Forman.

Re 35 USC 103

Claims 27-29, 40-41 and 44-45 are rejected under 35 USC 103 as being unpatentable over Forman (US 5,733,301). Claims 27-29 are directed to a medical balloon. The claims include the recitation that the medical balloon includes at least one segment having a ground or chemically etched surface. Forman does not disclose a balloon having at least one segments having a chemically etched or ground surface. Forman states (col. 2, lines 38-42):

Yet another object is to provide a process for selectively **ablatively** removing material from a balloon catheter and its dilatation balloon, to enhance catheter trackability and maneuverability without crystallization, embrittlement or other thermal degradation of material. **(emphasis added)**

Forman further states (col. 7, line 66 – col. 8, line 18):

Excimer laser ablation, sometimes also called ablative photo decomposition, is believed to have photo-chemical and photo-thermal aspects. The photo-chemical aspect involves

Application No.: 09/781,388
Filed: February 13, 2001

Amendment
Page 5

breaking chemical bonds to cause disassociation of molecules of the polymeric material subject to excimer laser energy. A highly localized and abrupt increase in pressure results, tending to eject material from the exposed area. The ejected material is heated, but rapidly removes heat from the treatment site by its ejection. Accordingly, any temperature increase at the treatment site is extremely brief, and little or no thermal effect results. At higher fluence levels, longer pulse durations and higher pulse frequencies, photo-thermal effects, which involve vibration of the polymeric molecules, become more apparent. While actual operating parameters can vary with the polymeric material and nature of material removal, the minimizing of thermal effects is important. Excessive concentrations of heat can cause crystallization or localized melting where the polymeric material may become brittle. In either event, catheter flexibility and maneuverability are adversely effected.

Conversely, by selecting a short wavelength (preferably 193 nm), shorter pulse durations, lower pulse frequencies and lower fluence levels, decomposition is primarily photo-chemical and thinning of the catheter balloon walls does not materially reduce balloon and catheter flexibility.

In short, Forman stresses the significance of the benefits of laser ablation, namely, not heating the balloon and of not causing local crystallization or embrittlement of the balloon associated with heating.

Given the importance that Forman attributes to not heating the balloon, it is surprising that a technique such as grinding or chemical etching would be suitable for removing material from a balloon. One would certainly expect, on the basis of Forman, that undesirable localized heating with the associated effects would accompany the use of grinding. One would also expect that chemical etching would be difficult to control and could have a deleterious effect on the balloon. It is surprising that grinding or chemical etching would prove suitable for use with such delicate materials as medical balloon materials.

As to etching, there is no teaching or suggestion in Forman that chemical etching would be suitable for removing material during the manufacture of a balloon.

As such, the instant claims are patentable over Forman.

The medical balloon of claim 40 also requires that at least one balloon portion selected from the group consisting of the body portion, the proximal cone portion, the distal cone portion, the proximal waist portion, the distal waist portion and any combination thereof, has a

Application No.: 09/781,388
Filed: February 13, 2001

Amendment
Page 6

ground surface. As discussed above, Forman neither teaches nor suggests a balloon having a ground surface. As such, claim 40 is patentable over Forman.

The medical balloon of claim 41 also requires that at least one balloon portion selected from the group consisting of the body portion, the proximal cone portion, the distal cone portion, the proximal waist portion, the distal waist portion and any combination thereof, has a chemically etched surface. As discussed above, Forman neither teaches nor suggests a balloon a portion of which has a chemically etched surface. As such, claim 41 is patentable over Forman.

The medical balloon of claim 44 also requires that at least one balloon portion selected from the group consisting of the body portion, the proximal cone portion, the distal cone portion, the proximal waist portion, the distal waist portion and any combination thereof, has a ground surface. As discussed above, Forman neither teaches nor suggests a balloon a portion of which has a ground surface. As such, claim 44 is patentable over Forman.

The medical balloon of claim 45 also requires that at least one balloon portion selected from the group consisting of the body portion, the proximal cone portion, the distal cone portion, the proximal waist portion, the distal waist portion and any combination thereof, has a chemically etched surface. As discussed above, Forman neither teaches nor suggests a balloon a portion of which has a chemically etched surface. As such, claim 45 is patentable over Forman.

CONCLUSION

In light of the above, the pending claims are believed to be in condition for allowance. Withdrawal of the rejections is respectfully requested as is notification of allowance.

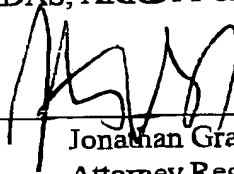
Application No.: 09/781,388
Filed: February 13, 2001

Amendment
Page 7

Respectfully submitted,
VIDAS, ARRETT & STEINKRAUS, P.A.

Date: April 26, 2002

By: _____



Jonathan Grad
Attorney Reg. No. 41,795

Suite 2000
6109 Blue Circle Drive
Minnetonka, Minnesota 55343-9185
Telephone No: (952) 563-3000
Facsimile No: (952) 563-3001

Application No. 09/781,388
Filed: February 13, 2001

Marked-Up Claims
Page 1

Please amend claims 27, 33, 40-42, 44 and 45 as follows:

27.(Amended) A medical balloon having:
a proximal waist portion have a proximal waist wall thickness;
a proximal cone portion having a proximal cone wall thickness;
a body portion having a body wall thickness;
a distal cone portion having a distal cone wall thickness; and
a distal waist portion having a distal waist wall thickness;
wherein the wall thickness of at least one balloon segment selected from the group consisting of the proximal waist, the proximal cone, the distal cone and the distal waist segments is less than the body wall thickness, the at least one segment having a chemically etched or ground surface [had material removed therefrom by grinding or chemical etching].

33.(Amended) A medical balloon comprising:
a body portion having a body wall thickness, a proximal cone portion having a proximal cone wall thickness, a proximal waist portion having a proximal waist wall thickness, a distal cone portion having a distal cone wall thickness, and a distal waist portion having a distal waist wall thickness, at least a portion of the balloon having a ground or chemically etched surface,
wherein at least one of the proximal waist wall thickness and the distal waist wall thickness is no thicker than at least one of the proximal cone wall thickness, the distal cone wall thickness, and the body wall thickness.

40. (Amended) The medical balloon of claim 33 wherein at least one balloon portion selected from the group consisting of the body portion, the proximal cone portion, the distal cone portion, the proximal waist portion, the distal waist portion and any combination thereof, has [had material removed therefrom by grinding] a ground surface.

41. (Amended) The medical balloon of claim 33 wherein at least one balloon portion selected from the group consisting of the body portion, the proximal cone portion, the distal cone portion, the proximal waist portion, the distal waist portion and any combination thereof, has [had material removed therefrom by chemical etching] a chemically etched surface.

42. (Amended) A medical balloon comprising:
a body portion having a body wall thickness;
a proximal cone portion, the proximal cone portion having a proximal cone wall thickness, the proximal cone wall thickness being no thicker than the body wall thickness;
a proximal waist portion, the proximal waist portion having a proximal waist wall thickness, the proximal waist wall thickness being no thicker than the proximal cone wall thickness;
a distal cone portion having a distal cone wall thickness, the distal cone wall thickness being no thicker than the body wall thickness; and

Application No. 09/781,388
Filed: February 13, 2001

Marked-Up Claims
Page 2

a distal waist portion having a distal waist wall thickness, the distal waist wall thickness being no thicker than the proximal cone wall thickness, at least a portion of the balloon having a ground or chemically etched surface.

44. (Amended) The medical balloon of claim 42 wherein at least one balloon portion selected from the group consisting of the body portion, the proximal cone portion, the distal cone portion, the proximal waist portion, the distal waist portion and any combination thereof, has a ground surface [had material removed therefrom by grinding].

45. (Amended) The medical balloon of claim 42 wherein at least one balloon portion selected from the group consisting of the body portion, the proximal cone portion, the distal cone portion, the proximal waist portion, the distal waist portion and any combination thereof, has [had material removed therefrom by chemical etching] a chemically etched surface.